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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,034	03/19/2001	Stephen L. Mayo	A-65353-6/RFT/RMS/RMK	3845
7590 10/15/2003			EXAMINER	
Robin M. Silva, Esq. DORSEY & WHITNEY LLP Four Embarcadero Center Suite 3400 San Francisco, CA 94111-4187			KIM, YOUNG J	
			ART UNIT	PAPER NUMBER
			1637	//
DATE MAILED: 10/15/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/812,034

Applicant(s)

MAYO ET AL.

Examiner

Young J. Kim

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 30,31,53 and 56-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30,31,53,56-79 and 83-86 is/are allowed.
- 6) ☒ Claim(s) 76-78 and 80-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This Office Action responds the Amendment received on August 11, 2003 (Paper No. 9).

#### ***Claim Objections***

The objection of claims 45 and 46 for being in improper form, made in the Office Action mailed on February 11, 2003 is withdrawn in view of the Amendment received on August 11, 2003, canceling the claims.

#### ***Claim Rejections - 35 USC § 112 – First paragraph***

The rejection of claims 47-50 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, made in the Office Action mailed on February 11, 2003 is withdrawn in view of the Amendment received on August 11, 2003, canceling the claims.

#### ***Rejection – Necessitated by Amendment***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 78 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a **New Matter** rejection.

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Applicants have submitted claim 78 drawn to an embodiment of modulating the protein backbone structure involved in the optimization. The specification provides no support for such limitation. The specification does provide for considering different amino acid side chains for a plurality of variable residue positions in the protein. The specification, however, does not provide any support for modulating the protein backbone structure involved in the optimization process.

***Claim Rejections - 35 USC § 112 – Second paragraph***

The rejection of claims 40, 57, and 58 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on February 11, 2003 is withdrawn in view of the Amendment received on August 11, 2003, canceling claim 40 and amending claims 57 and 58 to establish proper antecedent basis.

***Rejections – Necessitated by Amendment***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 76, 77, and 80-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 76 and its dependent claim 77 recite the limitation "said list." There is insufficient antecedent basis for this limitation in the claim.

Claim 80 and its dependent claims 81 and 82 are indefinite for the recitation of the phrase, "wherein step (c) comprises a second group for a second variable position has a second

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set of at least two amino acid side chains," because it is unclear what the claim is trying to achieve. For the purpose of prosecution, the phrase has been assumed to read, "wherein step (c) comprises a second group for a second variable position *having a second set of at least two amino acid side chains.*"

Claims 81 and 82 recite the limitation "said first and second amino acid side chains." There is insufficient antecedent basis for this limitation in the claim. For the purpose of prosecution, the phrase is assumed to read, "said at least two amino acid side chains."

### ***Double Patenting***

The rejection of claims 30-52 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,269,312 B1, made in the Office Action mailed on February 11, 2003 is withdrawn in view of the Amendment received on August 11, 2003, canceling claims 32-52, and further in view of the Terminal Disclaimer filed on August 13, 2003.

The rejection of claims 53-55 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,269,312 B1, made in the Office Action mailed on February 11, 2003 is withdrawn in view of the Amendment received on August 11, 2003, canceling claims 54 and 55, and further in view of the Terminal Disclaimer filed on August 13, 2003.

The rejection of claims 56-60 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 7, and 12 of U.S. Patent No. 6,269,312 B1,

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made in the Office Action mailed on February 11, 2003 is withdrawn in view of the Terminal Disclaimer filed on August 13, 2003.

### ***Conclusion***

Claims 76-78 and 80-82 are rejected. Claims 30, 31, 53, 56-79, and 83-86 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### ***Inquiries***


**Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (703)-308-3905. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If**

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applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

10/8/03

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

10/9/03